

REMARKS

Reconsideration of this application is respectfully requested in view of the amendments above and following remarks. Claims 28 to 37 were pending in the present application. Claims 28 to 37 were rejected. Claims 28, 33 and 36 have been amended. Presently, Claims 28 through 37 remain under consideration.

Claims 28 and 33 have been amended to delete the term “essentially” and to add the phrase “as the active ingredient”. Support for this amendment is found in the specification at p. 7, lines 20-27. Claim 36 has been amended to delete “essentially”. Support for this amendment is found throughout the specification as originally filed and in Example 5 where the 5 $\alpha$  reductase 2 inhibitor finasteride is the sole active ingredient.

Claim Rejections - 35 USC §103

Claims 28-37 were rejected under 35 USC §103(a) as being unpatentable over Goldman (US 5407944). In maintaining the rejection, the Examiner stated:

Claim 28 is directed to a method of treating androgenic alopecia consisting essentially of transversally [sic] administering to a person in need of such treatment a therapeutically effective amount of a 5  $\alpha$ -reductase 2 inhibitor; Claim 30 specifies administration by transdermal skin patch [sic]; Claim 33 specifies that the 5  $\alpha$ -reductase 2 inhibitor is 17 $\beta$ -(N-tert-butylcarbonyl)4-aza-5  $\alpha$ -androst-1-ene-3-one), otherwise known as a “Finasteride”; Claim 36 is directed to a skin patch consisting essentially of a 5  $\alpha$ -reductase 2 inhibitor.

Goldman (US'944, hereinafter) teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and a 5  $\alpha$ -reductase inhibitor (Column 2, lines 42-46; Column 6, lines 5-9), “A highly [sic] preferred inhibitor or ... 5  $\alpha$ -reductase for use in [Goldman's] compositions and methods” (Column 5, lines 43-44), indeed the only 5- $\alpha$ -reductase inhibitor specifically mentioned, is finasteride (Column 5, lines 43-62). While “each agent of the combination need not be administered in the same manner” (Column 2, lines 65-67), “in a highly preferred embodiment the selected agents are administered from a single

vehicle in unit dosage form, including tablet, capsule, and transderma patches or preparation” (Column 3, lines 7-10).

While Goldman does not specifically describe incorporating a 5  $\alpha$ -reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a “highly preferred [sic]” 5  $\alpha$ -reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic by transdermal administration of a pharmaceutical preparation, e.g., a transdermal skin patch, consisting essentially of a 5  $\alpha$ -reductase inhibitor, e.g., finasteride, in view of Goldman’s explicit suggestions.

“Consisting Essentially Of”

Applicants amend the claims and argues that the pending Claims 28-37 are patentably distinguish [sic] over Goldman in view of the transition phrase “consisting essentially of” (Request for reconsideration and withdrawal of the rejection, see Remark section at page 6, filed 1/31/05). According to applicants, the recitation of an active component in those claims “consisting essentially of” 5  $\alpha$ -reductase inhibitor (Claims 28-32) or finasteride (Claims 33-37) exclude a vasodilator or an estradiol disclosed by Goldman.

The examiner disagree [sic].

As stated in PPG Indus., Inc. v. Guardian Indus. Corp., 156 F.3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354 (Fed. Cir. 1998),

By using the term “consisting essentially of”, the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A “consisting essentially of” claim occupies a middle ground between closed claims that are written in a “consisting of” format and fully open claims that are drafted in a “comprising” format. (Emphasis added).

Here applicants’ argument that “consisting essentially of” excludes those vasodilator or estradiols of Goldman is an example of *ipse dixit* reasoning. Applicants do not describe the “basic and novel

properties of the invention”, or explain why or establish how the vasodilators or estradiols of Goldman materially affects those properties.

Additionally, it is apparent from applicant’s specification (page 7-9) that the composition of the claimed method may include a host of ingredients or additives. On this record, it is unclear why the vasodilators or estradiols of Goldman would “materially affect” the basic and novel properties of the invention and, accordingly, be excluded by the phrase “consisting essentially of”, whereas the host of ingredients listed in the specification do not materially affect the basic and novel properties of the invention and, accordingly, are included by the phrase “consisting essentially of”. Applicants have not made it clear, in the their specification or in their request for reconsideration, what they “regarded as constituting a material change in the c the basic and novel properties of the invention” [sic].


Applicants have amended Claims 28 and 33, from which Claims 29-32 and 34-35 depend, respectively to specify that the claimed method consists of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha reductase 2 inhibitor finasteride as the active ingredient. The amended claims clarify that Goldman’s vasodilator and/or estradiol are excluded from the presently claimed subject matter. Goldman teaches a method for promoting hair growth comprising administering a therapeutically effective amount of at least two active agents selected from vasodilators, estradiols, 5alpha reductase inhibitors, and salts, esters and prodrugs thereof. Goldman does not teach or suggest treating androgenic alopecia consisting of transdermally administering a therapeutically effective amount of a 5alpha reductase inhibitor/finasteride, as the active ingredient. Indeed, in the only exemplification from Goldman, the 5alpha reductase is used in prophetic examples (1) with a vasodilator and estradiol, in a 3 ingredient treatment, and (2) with a vasodilator and a 5alpha reductase inhibitor in a 2 ingredient combination.

Applicants have amended Claim 36, from which Claim 37 depends, to specify that the transdermal skin path “consists” of a 5alpha reductase 2 inhibitor as the active ingredient. Goldman does not teach or suggest a transdermal skin patch consisting of a 5alpha reductase 2 inhibitor as the active ingredient.

In view of the amendments and remarks above, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 28 to 37 in view of Goldman.

For the foregoing reasons, Applicants believe that with the present amendments, the instant application is in condition for allowance, or at least in better condition for appeal. If the Examiner has further questions or concerns regarding this application, she is invited to telephone the undersigned attorney at the number below.

Respectfully submitted,

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